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ABSTRACT

Behavioral interventions have focused primarily on early detection rather than the prevention of breast cancer; this trend is changing rapidly as chemoprevention agents, such as Tamoxifen, receive more attention. An important challenge is how to facilitate the review of Tamoxifen information among higher risk women who may benefit from its use. A second challenge is to understand how the format of conveying Tamoxifen's risks and benefits to affect women's (a) overall weighing of risks and benefits and (b) intentions to use Tamoxifen. Whether a woman reviews information on Tamoxifen depends, in part, on how she interprets her BC risk. The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to use Tamoxifen and talk to a health care provider about its use. Evaluating the effects of different formats, and understanding the psychosocial mechanisms through which they affect decision-making, will become increasingly important as more women consider Tamoxifen, other breast cancer chemopreventive agents (e.g. Raloxifen), and chemopreventive drugs for cancer more broadly.

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I. Introduction

The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to use Tamoxifen and talk to a health care provider about its use. The specific aims are to test how conveying (1) breast cancer risk as a frequency (e.g., 10 out of 10,000) or probability (e.g., .1%) affects perceived BC risks and negative emotions (e.g., fear, worry) about getting BC, the extent of processing information about Tamoxifen's risks and benefits (i.e., how much time is spent reviewing data on Tamoxifen), and intentions to use and talk to a health care provider about Tamoxifen use and (2) Tamoxifen's risks and benefits as frequencies or probabilities, individually and jointly interact with the BC risk format to affect women's weighing of the risks and benefits, intentions to use and talk with a health care provider about Tamoxifen use.

II. Body: <u>Accomplishments as Outlined in the Approved Statement of Work</u>

A. Recruitment and experimental procedures (Months 3-33)

Our original planned enrollment was 400 women. We are targeting recruitment for 200 women. In part, this lower target number is due to a delay in recruitment caused by a longer than expected time to get IRB approval from the DOD – about nine months. Further, we are finding a lower-than expected number of women who qualify -- ~14% versus the close to 17% we originally expected.

Recruitment letters were mailed starting September 2004. To date, there have been 1,291 recruitment letters mailed. 804 women have completed the screening, which equates to a 62% response rate. Of the 804 women screened, there were 693 ineligible and 111 women eligible for the study. Out of the 111 initially eligible women, 82 were ultimately eligible to complete the baseline and 80 were consented. Out of the 44 who initially qualified, 6 were lost and 38 withdrew at different points of the study. Among the 80 who consented, 79 women completed the baseline survey that began September 2004.

Among the 79 baseline surveys completed, 9 women withdrew at the lab that began in October 2004; further 3 were lost at lab and 1 was incomplete. Thus, 66 women were eligible for the lab interview and 62 women completed the lab with 4 labs pending future dates. 94% of the labs have been completed.

One month follow-up surveys began in December 2004. There have been 38 out of the 56 one-month follow-ups completed, 68%. There are 18 one-month pending for follow-up.

B. Interim analyses have been conducted.

(See appendices) Poster presentation Abstract from poster presented at the Era of Hope 2005-Department of Defense Breast Cancer Research Program Meeting in Philadelphia, PA.

III. Key Research Accomplishments

All survey instruments including the baseline phone survey, lab questionnaires and follow-up questionnaires have been finalized and approved by the Duke University Medical Center Institutional Review Board (IRB).

Two computer programs have been completed and are being utilized in the lab session. One program is a web-based program designed to present information on Tamoxifen's risks and benefits and the other program, e-prime, is used to assess participant's thoughts and feelings about their breast cancer risk and taking Tamoxifen.

As of May, 2005, we have recruited one third of our sample size and have received recruitment support from two Duke University Health System clinics which have seventeen (17) Duke Gynecologists and Nurse Practitioners.

IV. Reportable Outcomes

Interim study analyses have taken place. (See appendices) Poster presentation Abstract from poster presented at the Era of Hope 2005-Department of Defense Breast Cancer Research Program Meeting in Philadelphia, PA.

V. Conclusions

None

VI. References

None

VII. Appendices

Abstract from poster presented at the Era of Hope 2005-Department of Defense Breast Cancer Research Program Meeting in Philadelphia, PA

TITLE: HIGHER RISK WOMEN'S BASIC UNDERSTANDING AND INTEREST IN TAMOXIFEN FOR BREAST CANCER CHEMOPREVENTION

AUTHORS: ISAAC LIPKUS, PAUL MARCOM, AND ELLEN PETERS

Affiliations: Duke University Medical Center and Oregon Decisional Research Institute

Tamoxifen has been approved by the FDA as a chemopreventive agent against breast cancer for women who have a five-year breast cancer risk of 1.66% or greater. To date, very little it known about how women who qualify for tamoxifen perceive the risks and benefits of its use as conveyed in different communication formats. As part of a larger ongoing trial, 38 women recruited from OB/GYN clinics in central North Carolina and who qualified for tamoxifen were provided with a computerized decision aid that tailored five health risks and five health benefits of taking tamoxifen for five years. This information was provided numerically in a frequency or percentage format. After reviewing the information, participants were asked: 1) whether tamoxifen increased, decreased or did not affect their chances of experiencing the 10 health events mentioned, 2) for their overall weighing of the risks and benefits for self (1=benefits outweigh the risks by a lot to 5=risks outweigh the benefits by a lot) as well as for others, 3) interest in taking tamoxifen (1=not at all to 5=extremely), and 4) motivation and interest in talking to a health care provider about tamoxifen (1=not at all to 5=extremely). All women completed a measure of numeracy.

Participants were able to identify on average 7 out of 10 events correctly as to whether tamoxifen increased or decreased their chances of experiencing the health events. Women with greater numeracy (M =8.3 out of 11) were more likely to specify correctly how tamoxifen affected their chances of experiencing these events ($r=.59$, $p<.0001$). The numerical format did not affect understanding of the direction of these risks and benefits, although it was slightly better in the frequency than percentage format (M=7.6 vs. 6.8). Participants viewed there being more risks than benefits of taking tamoxifen for themselves versus other women their age and race (M=2.89 vs. 3.22, $p<.0001$). Further, they expressed slight to moderate levels of motivation and interest in talking to a health care provider (Ms=2.4 and 2.5, respectively) and slight interest in taking tamoxifen (M=1.9). Interest in using tamoxifen was higher among women whose actual benefits outweigh the risks ($r=.41$, $p<.02$).

These very preliminary data suggest that higher risk women after being exposed to numerical information have a fair understanding of tamoxifen's risks and benefits, especially among those more numerate, although there is room for improvement. Further, many of these women expressed little interest in using tamoxifen viewing the risks outweighing the benefits. Women may need further prognostic indicators (e.g., findings of atypia, BRCA1/2 mutations) before modifying their beliefs and interests in using tamoxifen for chemoprevention.

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